114TH CONGRESS 2D SESSION

S. 1915

AN ACT

- To direct the Secretary of Homeland Security to make anthrax vaccines available to emergency response providers, and for other purposes.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,

1 SECTION 1. SHORT TITLE.

- This Act may be cited as the "First Responder An-
- 3 thrax Preparedness Act".
- 4 SEC. 2. VOLUNTARY PRE-EVENT ANTHRAX VACCINATION
- 5 PILOT PROGRAM FOR EMERGENCY RE-
- 6 SPONSE PROVIDERS.
- 7 (a) Pilot Program.—
- 8 (1) Establishment.—The Secretary of Home-9 land Security, in coordination with the Secretary of 10 Health and Human Services, shall carry out a pilot 11 program to provide eligible anthrax vaccines from 12 Strategic National Stockpile under section 13 319F-2(a) of the Public Health Service Act (42 14 U.S.C. 247d-6b(a)) that will be nearing the end of 15 their labeled dates of use at the time such vaccines 16 are made available to States for administration to 17 emergency response providers who would be at high 18 risk of exposure to anthrax if such an attack should 19 occur and who voluntarily consent to such adminis-20 tration.
 - (2) Determination.—The Secretary of Health and Human Services shall determine whether an anthrax vaccine is eligible to be provided to the Secretary of Homeland Security for the pilot program described in paragraph (1) based on—

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1	(A) a determination that the vaccine is not
2	otherwise allotted for other purposes;
3	(B) a determination that the provision of
4	the vaccine will not reduce, or otherwise ad-
5	versely affect, the capability to meet projected
6	requirements for this product during a public
7	health emergency, including a significant reduc-
8	tion of available quantities of vaccine in the
9	Strategic National Stockpile; and
10	(C) such other considerations as deter-
11	mined appropriate by the Secretary of Health
12	and Human Services.
13	(3) Preliminary requirements.—Before im-
14	plementing the pilot program required under this
15	subsection, the Secretary of Homeland Security, in
16	coordination with the Secretary of Health and
17	Human Services, shall—
18	(A) establish a communication platform for
19	the pilot program;
20	(B) develop and deliver education and
21	training for the pilot program;
22	(C) conduct economic analysis of the pilot
23	program, including a preliminary estimate of
24	total costs and expected benefits;

1	(D) create a logistical platform for the an-
2	thrax vaccine request process under the pilot
3	program;
4	(E) establish goals and desired outcomes
5	for the pilot program; and
6	(F) establish a mechanism to reimburse
7	the Secretary of Health and Human Services
8	for—
9	(i) the costs of shipment and trans-
10	portation of such vaccines provided to the
11	Secretary of Homeland Security from the
12	Strategic National Stockpile under such
13	pilot program, including staff time directly
14	supporting such shipment and transpor-
15	tation; and
16	(ii) the amount, if any, by which the
17	warehousing costs of the Strategic Na-
18	tional Stockpile are increased in order to
19	operate such pilot program.
20	(4) Location.—
21	(A) IN GENERAL.—In carrying out the
22	pilot program required under this subsection,
23	the Secretary of Homeland Security shall select
24	not fewer than 2 nor more than 5 States for

voluntary participation in the pilot program.

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- (B) REQUIREMENT.—Each State that par-ticipates in the pilot program under this sub-section shall ensure that such participation is consistent with the All-Hazards Public Health Emergency Preparedness and Response Plan of the State developed under section 319C-1 of the Public Health Service Act (42 U.S.C. 247d-3a).
 - that participation in the pilot program under this subsection strategically increases State and local response readiness in the event of an anthrax release, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall provide guidance to participating States and units of local government on identifying emergency response providers who are at high risk of exposure to anthrax.
 - (6) DISTRIBUTION OF INFORMATION.—The Secretary of Homeland Security shall require that each State that participates in the pilot program under this subsection submit a written certification to the Secretary of Homeland Security stating that each emergency response provider within the State that participates in the pilot program is provided

1	with disclosures and educational materials des-
2	ignated by the Secretary of Health and Human
3	Services, which may include—
4	(A) materials regarding the associated ben-
5	efits and risks of any vaccine provided under
6	the pilot program, and of exposure to anthrax;
7	(B) additional material consistent with the
8	Centers for Disease Control and Prevention's
9	clinical guidance; and
10	(C) notice that the Federal Government is
11	not obligated to continue providing anthrax vac-
12	cine after the date on which the pilot program
13	ends.
14	(7) Memorandum of understanding.—Be-
15	fore implementing the pilot program under this sub-
16	section, the Secretary of Homeland Security shall
17	enter into a memorandum of understanding with the
18	Secretary of Health and Human Services to—
19	(A) define the roles and responsibilities of
20	each Department for the pilot program; and
21	(B) establish other performance metrics
22	and policies for the pilot program, as appro-
23	priate.
24	(8) Report.—

1	(A) In General.—Notwithstanding sub-
2	section (c), not later than 1 year after the date
3	on which the initial vaccines are administered
4	under this section, and annually thereafter until
5	1 year after the completion of the pilot program
6	under this section, the Secretary of Homeland
7	Security, in coordination with the Secretary of
8	Health and Human Services, shall submit to
9	the Committee on Homeland Security and the
10	Committee on Energy and Commerce of the
11	House of Representatives and the Committee
12	on Homeland Security and Governmental Af-
13	fairs and the Committee on Health, Education,
14	Labor, and Pensions of the Senate a report on
15	the progress and results of the pilot program,
16	including—
17	(i) a detailed tabulation of the costs to
18	administer the program, including—
19	(I) total costs for management
20	and administration;
21	(II) total costs to ship vaccines;
22	(III) total number of full-time
23	equivalents allocated to the program;
24	and

1	(IV) total costs to the Strategic
2	National Stockpile;
3	(ii) the number and percentage of eli-
4	gible emergency response providers, as de-
5	termined by each pilot location, that volun-
6	teer to participate;
7	(iii) the degree to which participants
8	complete the vaccine regimen;
9	(iv) the total number of doses of vac-
10	cine administered; and
11	(v) recommendations to improve ini-
12	tial and recurrent participation in the pilot
13	program.
14	(B) Final report.—The final report re-
15	quired under subparagraph (A) shall—
16	(i) consider whether the pilot program
17	required under this subsection should con-
18	tinue after the date described in subsection
19	(e); and
20	(ii) include—
21	(I) an analysis of the costs and
22	benefits of continuing the program to
23	provide anthrax vaccines to emergency
24	response providers;

1	(II) an explanation of the eco-
2	nomic, health, and other risks and
3	benefits of administering vaccines
4	through the pilot program rather than
5	post-event treatment; and
6	(III) in the case of a rec-
7	ommendation under clause (i) to con-
8	tinue the pilot program after the date
9	described in subsection (c), a plan
10	under which the pilot program could
11	be continued.
12	(b) DEADLINE FOR IMPLEMENTATION.—Not later
13	than 1 year after the date of enactment of this Act, the
14	Secretary of Homeland Security shall begin implementing
15	the pilot program under this section.
16	(c) Sunset.—The authority to carry out the pilot
17	program under this section shall expire on the date that
18	is 5 years after the date of enactment of this Act.
	Passed the Senate November 16, 2016.
	Attest:

Secretary.

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